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AUG 26 1994

#38

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fisher's Lane, Room 11-44  
Rockville, MD 20857

Dear Mr. Wilson:

This is a corrected copy of my previous letter of August 22, 1994, regarding the filing of an application for extension of the patent term of U.S. Patent No. 4,978,655 issued on December 18, 1990. The previous letter inadvertently omitted the filing date of the application. The letter should have stated that the application was filed on August 19, 1994, under 35 USC § 156.

As noted in my previous letter, since a determination has not been made whether the patent in question claims a product which is subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 USC § 156(d)(2)(A). I await your assistance in confirming that the product identified in the application has been subjected to a regulatory review period within the meaning of 35 USC § 156(g) before its commercial marketing or use. This communication is NOT to be considered as notice which may be made in the future pursuant to 35 USC § 156(d)(2)(A).

Our review of the application to date indicates that the subject matter would be eligible for extension of the patent term under 35 USC § 156.

*C. E. Van Horn*

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Charles E. Van Horn  
Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Dominic M. Mezzapelle  
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